# 2. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS



Medicon Fixit Headrest System

***MEDICON eG***

(As required by Section 807.92)

## 2.1 Submitter (807.92 (a) (1))

MEDICON eG
Gaensaecker 15
D-78532 Tuttlingen
Germany

Tel. +49 7462 2009 0
Fax: +49 7462 200950
eMail: sales@medicon.de

## 2.2 Date Summary Prepared: (807.92 (a) (1))

November 2009

## 2.3 Device Names (807.92 (a) (2))

| | |
|---|---|
| Proprietary: | Medicon Fixit Headrest System |
| Common name: | Neurosurgical Head Holder |
| Device: | Holder, Head, Neurosurgical (Skull Clamp) |
| Classification name: | Neurological Head Holder |
| Classification Code(s) | HBL, 882.4460 |
| Device Class | Class II |

## 2.4 Reason for Submission: ((807.81(2))

New Device

## 2.5 Predicate Device (807.92(a)(3))

The Medicon FIXIT Headrest System is substantially equivalent to the commercially marketed predicate device and does not raise new issues of safety and effectiveness.

- Schaerer Mayfield Infinity Skull Clamp, Integra Lifesciences Corp. (K051440)
- Doro Headrest System, PMI Freiburg, Germany (K001808)
- PSI Skull Clamp, V. Mueller (K002275)
- Radiolucent Head Frame, Mizuho (K955012)
- Skull Clamp, Codman (K912011)
- Mayfield A-2000 Skull Clamp, OHIO Medical (K932807)

For Predicate Device Catalogs please see **Exhibit 4-9**.

## 2.6 Device Description

The Medicon Fixit Head Rest System is made from one part, not 2 parts as the competitors systems. The Medicon clamp is designed to prevent closing by accident. The pistol handle with safety lock allows the surgeon a one-hand-use of the clamp. Furthermore, the movable parts are reduced to a minimum. The locking mechanism can be loaded with more than 90 kg.

There is a variety of pin holders available. The choice of pin holders very much depends on the preference of the surgeon, the clinical indication and the type of position of the skull.

The pins are made from Titanium and stainless steel and are delivered non-sterile. The pins are re-usable. At the pistol grip side there is a pressure indicator. By turning the screw the surgeon fixes the skull with a fine-adjustment.

Hydraulicus allows via a foot pedal to open and close the connector between the head rest clamp and the operating table which enables the surgeon to manipulate the head rest and / or the patient's head manually and at the same time open and close the locking mechanism with the foot peal.

The base unit is connected to the operating table. As the base unit is equipped with a quick coupling, it may be adapted easily and fast to any operating table.

## 2.7 Intended Use (807.92 (a) (5))

The Medicon FIXIT head rest system is designed to provide stabilization and rigid fixation of patient's skull during surgical operations. It is indicated for neurosurgical operative procedures.

## 2.8 Environment of Use

Medicon`s FIXIT Headrest System is intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers. .

Within these facilities the Medicon Fixit Headrest System may be located in areas such as operating rooms for surgery where sterile instruments are used.

## 2.9 Difference in Design and Technological Characteristics when compared to SE Devices (807.92 (a) (6))

**Material**:
Patient contact material for all Headrest Systems consists of titanium or stainless steel. Contact device are the skull pins.

**Design:**
The design is very similar between the systems. All Headrest Systems consist of skull pins, skull pin holder and Headrest frame. The Medicon design offers also a quick lock, a variety of Skull pin holders and a one part Headrest frame.

## 2.10 Industry Standards: (807.92 (d))

No applicable industry standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Medicon`s Fixit Headrest System is manufactured in accordance with the MDD 93/42 EEC (please find enclosed the certificate from the notified body), the ISO and the German DIN Standards. Furthermore, the Medicon e. G. has received EN ISO 13485 – 2003 certification.

## 2.11 Information Bearing on the Safety and Effectiveness: (807.92 (b) (3))

The handling of the Medicon Fixit Headrest System is identical or substantially equivalent to the other commercially available headrest systems. The slight differences in design and size do not adversely affect the safety and effectiveness of this device.

## 2.12 Comparison with predicate devices (table)

The Medicon`s Fixit Headrest System including tools and accessories claims substantial equivalence to other currently marketed headrest systems. This claim is based on the SE Table and the detailed information provided in the additional document named SE Comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Medicon eG
% Ms. Tina Volkmer
Assistant Research and Development
Gaensaecker 15
D-78532 Tuttlingen, Germany

MAR 10 2010

Re: K083803
Trade/Device Name: Medicon Fixit Headrest Clamp System
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 18, 2010
Received: March 05, 2010

Dear Ms. Volkmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083803



FDA CDRH DMC

JAN 20 2010

Received

**APPENDIX 1**

**Indications for Use**

**510(k) Number** K083803

**Device Name** Medicon Fixit Headrest Clamp System

The Medicon FIXIT head rest system is designed to provide stabilization and rigid fixation of patient's skull during surgical operations. It is indicated for neurosurgical operative procedures.

Prescription Use__X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083803